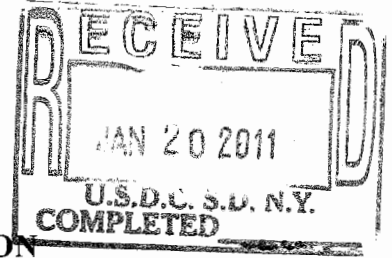


11 CV 0429

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

MARTIN SLOVE and LINDA SLOVE,  
Individually and On Behalf of All Others  
Similarly Situated,

Plaintiffs,

v.

MELA SCIENCES, INC., JOSEPH V. GULFO,  
RICHARD I. STEINHART, and BREAUX  
CASTLEMAN,

Defendants.

Case No.

CLASS ACTION

COMPLAINT  
FOR VIOLATIONS OF  
FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

OVERVIEW

1. This is a federal class action on behalf of purchasers of MELA Sciences, Inc. f/k/a Electro-Optical Sciences, Inc. ("MELA" or the "Company") securities including purchasers and sellers of call options and put options between February 13, 2009 and November 15, 2010, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). MELA is a medical device company that focuses on the design and development of a non-invasive, point-of-care instrument to assist in the early diagnosis of melanoma. As alleged herein, Defendants published a series of materially false and misleading statements that Defendants knew and/or recklessly disregarded were materially false and misleading at the time of publication, and that omitted to reveal material information necessary to make Defendants' statements, in light of such omissions, not materially false and misleading.

2. MELA's flagship product, MelaFind, features a hand-held imaging device that emits multiple wavelengths of light to capture images of suspicious pigmented skin lesions and extracts data. This product uses automatic image analysis and statistical pattern recognition to help identify lesions to be considered for biopsy to rule out melanoma.

3. The Company entered into a binding Protocol Agreement the United States Food and Drug Administration (“FDA”), which is an agreement for the conduct of the pivotal trial in order to establish the safety and effectiveness of MelaFind. The Company noted that the data accrual phase of the MelaFind pivotal trial was completed in the third quarter of 2008 and the image processing classification algorithms were finalized in the fourth quarter.

4. Nevertheless, throughout the Class Period, Defendants conditioned investors to believe that FDA approval of MelaFind would be forthcoming through a host of materially false and misleading statements regarding the status of MelaFind’s ongoing clinical studies, and the safety and efficacy of the Company’s products. For instance, on February 13, 2009, Defendants announced “*positive top-line results of its pivotal trial of MelaFind, a non-invasive, point-of-care instrument to assist in the early detection of melanoma, the deadliest form of skin cancer...*”

5. In touting positive aspects of MelaFind, Defendants were able to, among other things: (a) deceive the investing public regarding the Company’s business, operations, management, future business prospects and the intrinsic value of MELA’s common stock; (b) deceive the investing public regarding MELA’s business and management; (c) deceive the investing public regarding the efficacy of MelaFind and its prospects for FDA approval; (d) enable Defendants to sell almost \$79 million of MELA’s common stock to the public while in possession of material adverse non-public information about the Company; and (e) cause plaintiffs and other members of the Class to purchase MELA securities at artificially inflated prices.

6. On November 16, 2010, it was reported, in part, that MelaFind “*could cause harm because of the potential for misdiagnosis,*” and that “*FDA staff pointed to numerous problems*

*with Mela's study of the device, called MelaFind, including a significant lack of data, and urged a new clinical trial."*

7. On this news, investors were shocked to learn the truth regarding MelaFind. As a result, MELA's stock price plummeted approximately 54% as the artificial inflation caused by Defendants' material misrepresentations during the Class Period was removed, thereby harming plaintiffs and the Class who purchased the Company's shares at artificially inflated prices.

### **JURISDICTION AND VENUE**

8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

10. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). MELA maintains its principal place of business in this District and many of the acts and practices complained of occurred in substantial part herein.

11. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

### **PARTIES**

12. Plaintiffs Martin Slove and Linda Slove, as set forth in the accompanying certification, incorporated by reference herein, purchased MELA securities and purchased and sold put options of MELA at artificially inflated prices during the Class Period and were

damaged thereby.

13. Defendant MELA Sciences, Inc. is a corporation organized under the laws of the state of Delaware, maintaining its principal place of business at 50 South Buckhout Street, Suite 1, Irvington, New York 10533. The Company was formerly known as Electro-Optical Sciences, Inc. and changed its name to MELA Sciences, Inc. in April 2010.

14. According to the Company's profile listed on finance yahoo.com, MELA operates as a medical device company that focuses on the design and development of a non-invasive, point-of-care instrument to assist in the early diagnosis of melanoma. MELA's principal flagship product, MelaFind, features a band-held imaging device that emits multiple wavelengths of light to capture images of suspicious pigmented skin lesions and extract data. This product uses automatic image analysis and statistical pattern recognition to help identify lesions to be considered for biopsy to rule out melanoma. The components of the MelaFind system include: a *hand-held imaging device*, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red); a *proprietary database* of pigmented skin lesions, is believed to be the largest in the U.S.; and, *lesion classifiers*, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions. MELA filed the MelaFind pre-market approval application with the FDA in June 2009.

#### **Individual Defendants**

15. Defendant Joseph V. Gulfo ("Gulfo") is and was, during the relevant period, President, Chief Executive Officer, and a Director of the Company. During the Class Period, defendant Gulfo signed and certified the Company's SEC filings, including MELA's Form 10-Q and 10-K. Also during the Class Period, Defendant Gulfo was also responsible for the registration and sale of almost \$79 million of MELA common stock to the investing public,

while in possession of material non-public information about the Company.

16. Defendant Richard I. Steinhart ("Steinhart") is and was, during the relevant period, Vice-President of Finance, Chief Financial Officer, Treasurer, and Secretary of the Company. During the Class Period, Defendant Steinhart signed and certified the Company's SEC filings, including MELA's Forms 10-Q and 10-K. Also during the Class Period, Defendant Steinhart was also responsible for the registration and sale of almost \$79 million of MELA common stock to the investing public, while in possession of material non-public information about the Company.

17. Defendant Breaux Castleman ("Castleman") is and was, during the relevant period, Chairman of the Board of Directors of the Company. During the Class Period, Defendant Castleman signed the Company's Forms 10-K. In June 2003, the Company entered into a consulting agreement with Defendant Castleman for consulting services related to the FDA approval of MelaFind, and the Company's business and financial strategy. Under this agreement, Defendant Castleman receives compensation for each month of services rendered. Also during the Class Period, Defendant Castleman was also responsible for the registration and sale of almost \$79 million of MELA common stock to the investing public, while in possession of material non-public information about the Company.

18. The defendants referenced above in ¶¶15-17 are referred to herein as the "Individual Defendants."

19. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of MELA's quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the



Company's reports and press releases alleged to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company and their access to material non-public information, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. As a result, the Individual Defendants are liable for the false and misleading statements pleaded herein.

20. Each of the defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of MELA securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (a) deceived the investing public regarding the Company's business, operations, management, future business prospects and the intrinsic value of MELA's securities; (b) deceived the investing public regarding MELA's business and management; (c) deceived the investing public regarding the efficacy of MelaFind and its prospects for FDA approval; (d) enabled Defendants to sell almost \$79 million of MELA's common stock to the public while in possession of material adverse non-public information about the Company; and (e) caused plaintiffs and other members of the Class to purchase MELA securities at artificially inflated prices.

#### **PLAINTIFFS' CLASS ACTION ALLEGATIONS**

21. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf a Class, consisting of all those who purchased or otherwise acquired MELA securities including those who purchased and sold call options and put options between February 13, 2009 and November 15, 2010, inclusive (the "Class") and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the

Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

22. The members of the Class are so numerous that joinder is impracticable. Throughout the Class Period, MELA securities were actively traded on the Nasdaq. As of November 1, 2010, the Company reported that 25,253,136 shares of its securities were outstanding. While the exact number of Class Members is unknown to plaintiffs at this time and can only be ascertained through appropriate discovery, plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other member of the Class may be identified from records maintained by MELA or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

23. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of the federal securities laws.

24. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

25. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members. Among the questions of law and fact common to the Class are:

- (a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;
- (b) Whether statements made by Defendants to the investing public during the

Class Period misrepresented material facts about the business, operations, and management of MELA, and,

(c) to what extent the members of the Class have sustained damages and the proper measure of such damages.

26. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class Members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

#### **REGULATORY FRAMEWORK GOVERNING CLINICAL TRIALS**

27. With respect the Company's clinical trials of MELA, Defendants were subject to the following regulations promulgated by the FDA.

#### **Review of ongoing Investigations**

28. Concerning review of ongoing investigations, 21 CFR § 312.56 provides, in pertinent part:

(a) The sponsor shall monitor the progress of all clinical investigations being conducted under its IND.

\* \* \*

(c) The sponsor shall review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator. The sponsors shall make such reports to FDA regarding information relevant to the safety of the drug as are required under § 312.32. The sponsor shall make annual reports on the progress of the investigation in accordance with § 312.33.



### Annual Reports

29. In regard to the submission of annual reports to the FDA, 21 CFR § 312.33 provides:

A sponsor shall within 60 days of the anniversary date that the IND went into effect, submit a brief report of the progress of the investigation that includes:

(a) Individual study information. A brief summary of the status of each study in progress and each study completed during the previous year. ***The summary is required to include the following information for each study:***

- (1) The title of the study (with any appropriate study identifiers such as protocol number), its purpose, a brief statement identifying the patient population, and a statement as to whether the study is completed.
- (2) The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, tabulated by age group, gender, and race; the number whose participation in the study was completed as planned; and the number who dropped out of the study for any reason.
- (3) ***If the study has been completed, or if interim results are known, a brief description of any available study results.***

(b) Summary information. Information obtained during the previous year's clinical and nonclinical investigations, including:

- (1) ***A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system.***
- (2) A summary of all IND safety reports submitted during the past year.
- (3) A list of subjects who died during participation in the investigation, with the cause of death for each subject.
- (4) A list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related.
- (5) ***A brief description of what, if anything, was obtained that is pertinent to an understanding of the drug's actions, including, for example, information about dose response, information from controlled trials, and information about bioavailability.***

- (6) *A list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings.*
- (7) A summary of any significant manufacturing or microbiological changes made during the past year.
- (c) A description of the general investigational plan for the coming year to replace that submitted 1 year earlier. The general investigational plan shall contain the information required under § 312.23(a)(3)(iv).
- (d) If the investigator brochure has been revised, a description of the revision and a copy of the new brochure.
- (e) A description of any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.
- (f) A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.
- (g) If desired by the sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.

[Emphasis added].

### **SCIENTER ALLEGATIONS**

#### **Defendants' Positions of Authority and Control**

30. As alleged herein, Defendants acted with scienter in that each Defendant knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and, knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants participated in the fraudulent scheme alleged by virtue of their receipt of information reflecting

the true facts regarding MELA, their control over the Company's alleged materially misleading misstatements, and/or their associations with the Company, which made them privy to confidential proprietary information concerning MELA and MelaFind.

31. Defendants were motivated to materially misrepresent to the SEC and investors the true condition of MELA and the true facts about MelaFind because, in touting positive aspects of MelaFind, Defendants were able to, and did: (a) deceive the investing public regarding the Company's business, operations, management, future business prospects and the intrinsic value of MELA's securities; (b) deceive the investing public regarding MELA's business, management; (c) deceive the investing public regarding the efficacy of MelaFind and its prospects for FDA approval; (d) enable defendants to sell almost \$79 million of MELA's common stock to the public while in possession of material adverse non-public information about the Company; and (e) caused plaintiffs and other members of the Class to purchase MELA securities at artificially inflated prices.

**DEFENDANTS' MATERIALLY FALSE AND MISLEADING  
STATEMENTS MADE DURING THE CLASS PERIOD**

32. The Class Period begins on February 13, 2009. On that day, Defendants issued a press release touting positive news about its flagship product, MelaFind. The release stated, in part, the following:

IRVINGTON, NY (February 13, 2009) - Electro-Optical Sciences, Inc. ("EOS") (NASDAQ: MELA) today ***announced positive top-line results of its pivotal trial of MelaFind, a non-invasive, point-of-care instrument to assist in the early detection of melanoma, the deadliest form of skin cancer. The blinded study, conducted at seven centers across the US, included 1,831 pigmented skin lesions from 1,383 patients, making this the largest prospective study ever conducted in melanoma detection.*** EOS is working to complete its Pre-Market Approval (PMA) application and expects to file it with the US Food and Drug Administration (FDA) shortly.

*“MelaFind appears to be an excellent tool to help detect melanoma at the earliest, most treatable stage,”* said Gary D. Monheit, M.D., Associate Clinical Professor of Dermatology at the University of Alabama in Birmingham and the lead investigator for the MelaFind pivotal trial. “With no cure for late stage melanoma, early detection is our best defense against this cancer, which has reached epidemic proportions.”

Prior to the start of the study, BOS and the FDA entered into a binding protocol agreement to stipulate the sensitivity and specificity endpoints that should be used to determine the safety and effectiveness of MelaFind.

*MelaFind detected 112 of 114 (98% sensitivity; lower confidence bound of 95%) melanomas that were eligible and evaluable for primary sensitivity endpoint analysis, and 125 of 127 (98% sensitivity; lower confidence bound greater than 95%) melanomas overall.* The protocol agreement calls for sensitivity endpoints of greater than 95% lower confidence bound.

*MelaFind’s specificity, the ability to accurately rule out disease, was significantly superior (9.5%) to that of the study dermatologists (3.7%), who are skin cancer experts (p-value less than 0.02).* The protocol agreement calls for MelaFind to be more specific than the study physicians at a p-value<sup>2</sup> of less than 0.05.

*Almost half of the melanomas in the study were melanoma in situ, the most curable yet most difficult form of melanoma to detect.* [Emphasis added].

33. On March 2, 2009, the Company filed its Form 10-K for the fiscal year ending December 31, 2008, signed by Defendants Gulfo, Steinhart, and Castleman, and certified by Defendants Gulfo and Steinhart. The 2008 Form 10-K also reiterated many of the statements made in the February 13, 2009 release, including that MelaFind received “positive top line results from the MelaFind pivotal clinical trial.” The 2008 Form 10-K further touted results of the MelaFind trial, stating, in part, the following:

To date, MelaFind® has been developed, trained and tested on over 9,000 skin lesions from over 7,000 patients at over 30 clinics. *Our clinical studies have demonstrated that MelaFind® is highly sensitive for melanoma in situ and minimally invasive melanomas, and results in fewer false positive biopsies than skin cancer experts.* Furthermore, reader studies have demonstrated that MelaFind® detected more melanomas than dermatologists, including skin cancer experts.



We believe that with the assistance provided by MelaFind®, physicians could diagnose more melanomas at the earliest, most curable stages with *fewer false positive biopsies*, which would reduce both treatment costs and the number of unnecessary biopsies, and improve quality of life. [Emphases added].

34. In addition to the foregoing, Defendants also used the 2008 Form 10-K to condition investors to believe that the Company had already complied with the FDA's regulatory framework and had already satisfied certain parameters indicated in the Protocol Agreement with the FDA, including, in part, the following:

In late 2004, we entered into a binding Protocol Agreement with the FDA for our pivotal clinical study. A pivotal clinical trial is a blinded clinical study that is used by the FDA as the basis for determining the effectiveness of a device in a PMA application. The Protocol Agreement specified the inclusion criteria (description of patients and lesions eligible for the trial), sample size, endpoints, and performance criteria necessary to establish the safety and effectiveness of MelaFind®. The Protocol Agreement requires that the study include at least 1,200 pigmented skin lesions and at least 93 eligible melanomas for analysis. *The data accrual phase of the MelaFind pivotal trial was completed in the third quarter of 2008.* [Emphasis added.]

35. As stated above, the 2008 Form 10-K also repeated many of the statements contained in the February 13, 2009 release concerning the "top-line" results of its pivotal trial. In addition, however, defendants also included in the 2009 Form 10-K, the following:

In order to generate a comparison with dermatologists' ability to accurately detect melanoma, the Company conducted a parallel pilot readers' study with a different group of 39 dermatologists. *Using images and clinical histories of 23 randomly selected melanomas from the pivotal study, this group of dermatologists, on average, would have decided to biopsy only approximately 18 (80%) of the melanomas, whereas the MelaFind® result would have led to a biopsy of 22 of the melanomas (biopsy sensitivity 96%).* [Emphases added].

36. In addition to making substantially similar statements concerning the Company operations, including expenses, costs and ratios, as had been published previously, the 2008



Form 10-K also provided statements concerning the Company's controls and procedures, as follows:

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our company's management, with the participation of our chief executive officer and our chief financial officer, has evaluated the effectiveness of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities and Exchange Act of 1934) as of December 31, 2008.

Based on such evaluation, our chief executive officer and our chief financial officer have concluded that, as of December 31, 2008, our disclosure controls and procedures were effective to ensure that the information we are required to disclose in reports that we file or submit to the SEC is (1) recorded, processed, summarized and reported within the time periods specified under the rules and forms of the SEC and (2) accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

37. In addition to the foregoing, the Company's 2008 Form 10-K also contained certifications by Defendants Gulfo and Steinhart that attested to the purported accuracy and completeness of the Company's financial and operational reports, as follows:

1. I have reviewed this report on Form 10-K of Electro-Optical Sciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal

control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(t)) for the registrant and have:

- (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

- (a) all significant deficiencies and material weaknesses in the design or operations of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) any fraud whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Joseph V. Gulfo, M.D.  
Joseph V. Gulfo, M.D.

President and Chief Financial Officer  
(Principal Executive Officer)

Date: March 2, 2009

\* \* \*

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President and Chief Financial Officer  
(Principal Accounting and Financial Officer)

Date: March 2, 2009

38. Defendants Gulfo and Steinhart also certified that the information contained in the 2008 Form 10-K "fairly presents, in all material respects, the financial condition and results of operations of the Company," as follows:

**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER  
AND CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT  
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of Electro-Optical Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's Annual Report on Form 10-K *for* the period ended December 31, 2008 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo, M.D.  
Joseph V. Gulfo, M.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

March 2, 2009

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)

March 2, 2009

39. The statements made by Defendants and contained in the Company's February 13, 2009 release and in the Company's 2008 Form 10-K were each materially false and misleading when made, and were known by Defendants to be false or were recklessly disregarded as such thereby, for the following reasons, among others:

(a) Defendants failed to disclose that MelaFind's 98 percent accuracy in detecting melanoma skin cancers was enhanced by the fact that all the lesions entered into the study were initially flagged as being possibly cancerous by dermatologists and that this made it easier for the device to accurately diagnose melanoma;

(b) Defendants failed to disclose that despite the enriched pool of lesions entered into the phase III study, MelaFind still missed three melanomas, accurately diagnosing 172 of 175 lesions;

(c) Defendants failed to disclose that the Company had no data to prove that MelaFind's sensitivity is greater than that of dermatologists who participated in the study;

(d) Defendants failed to disclose that MelaFind does not significantly reduce the number of biopsies performed by dermatologists;

(e) Defendants failed to disclose that the clinical benefit of MelaFind is questionable when borderline lesions (the more difficult-to-diagnose cases) are added to melanomas in the analysis of the phase III data;

(f) Defendants failed to disclose that MelaFind's biopsy ratio was 7.6 to 1 compared to a biopsy ratio for dermatologists of 7.9 to 1 -- essentially equal;

(g) Defendants failed to disclose that the Company's clinical studies were defectively designed;

(h) Defendants failed to disclose that, as a result of the foregoing, FDA approval of MelaFind foreseeably would not be forthcoming;

(i) Defendants misrepresented the significance of the FDA's concerns as detailed in the Agency's March 19, 2010 series of questions and notification that the MelaFind PMA was not approvable;

(j) Defendants conditioned the market and investors to believe, until the full truth became known, that MelaFind was foreseeably going to be approved by the FDA in the near term;

(k) Throughout the Class Period, it was also not true that MELA contained adequate systems of internal operational or financial controls, such that MELA's reported financial statements were true, accurate or reliable; and

(l) As a result of the aforementioned adverse conditions which Defendants failed to disclose, throughout the Class Period, Defendants lacked any reasonable basis to claim that MELA was operating according to plan, or that MELA could achieve guidance sponsored and/or endorsed by Defendants.

40. Following the publication of these materially false and misleading statements that had the effect of artificially inflating the price of Company shares, on May 8, 2009, the Company announced that it had received a commitment for an additional \$45 million in equity financing. That day, Defendants published a release that stated, in part, the following:

IRVINGTON, NY, May 08, 2009 (MARKETWIRE via COMTEX) – Electro-Optical Sciences, Inc. (“EOS”) (NASDAQ: MELA) today announced that it has entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited, a private investment group, in which Kingsbridge has committed to provide, at the companies sole discretion up to \$45 million in cash during the next three years, through the purchase of newly-issued shares of Electro-Optical Science's common stock.



“This financing facility provides us great flexibility in choosing if, and when, to access funds, thereby minimizing shareholder dilution. We view this as an important secondary source of capital to that of more traditional equity financings,” said Joseph V. Gulfo, M.D., President and CEO of Electro-Optical Sciences. “The funds are available to US as we proceed through the regulatory pathway and commercialization process for MelaFind, our non-invasive, point of care, computerized system for early melanoma detection.”

\* \* \*

In connection with the CEFF, the company issued a warrant to Kingsbridge to purchase 200,000 shares of common stock at \$11.35 per share, representing a 50% premium to the average closing price of the company's common stock for the five days preceding the signing of the CEFF agreement.

The company may access capital under the CEFF by providing Kingsbridge with common stock at discounts ranging from six to ten percent, depending on the average market price of EOS' common stock during the applicable pricing period. The CEFF does not impose any material restrictions on EOS' operating or financial activities. During the term of the CEFF, Kingsbridge is prohibited from engaging in any short selling or derivative transactions related to BOS' common stock.

41. On May 11, 2009, the Company filed its Form 10-Q, for the first quarter ended March 31, 2009, signed by Defendant Steinhart, and certified by Defendants Gulfo and Steinhart. Again, the Company's report conditioned investors to believe that MelaFind received “positive top line results from the MelaFind pivotal clinical trial.” In addition to the foregoing, the Form 10-Q again conditioned investors to believe that the Company maintained an adequate system of internal controls, as follows:

Based on their evaluation as of March 31, 2009, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

42. The Form 10-Q again contained Certifications by Defendants Gulfo and Steinhart that continued to certify that the information contained in the Form 10-Q “fairly presents, in all material respects, the financial condition and results of operations of the Company,” as follows:

**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER  
AND CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT  
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of Electro-Optical Sciences, Inc. (the “Company”) hereby certifies to his knowledge that the Company’s Annual Report on Form 10-K for the period ended December 31, 2008 (the “Report”), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo, M.D.  
Joseph V. Gulfo, M.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

May 11, 2009

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)

May 11, 2009

43. On June 4, 2009, Defendants published a release heralding the Company’s submission to the FDA of a Pre-Market Approval Application, that again touted the positive results announced by the Company in February 2009. This release stated, in part, the following:

Electro-Optical Sciences, Inc. (“EOS”) (NASDAQ: MELA) today announced the submission to the United States Food and Drug Administration (FDA) of its Premarket Approval (PMA) application for MelaFind®, a non-invasive, point-of care instrument to assist in the early diagnosis of melanoma, the leading cause of death from skin cancer.

Positive top line data from the MelaFind pivotal study, the largest prospective clinical study ever conducted in melanoma detection, were announced in February and subsequently presented at several major international dermatology meetings in March and May of this year. The company's final analysis of the data demonstrated that for all subgroups analyzed, the sensitivity of MelaFind was greater than 95% (lower confidence bound) and MelaFind specificity was statistically significantly higher than that of study clinicians. As announced previously, the FDA has granted Expedited Review for the MelaFind PMA.

"We believe the final results of the MelaFind pivotal study met the study endpoints and that the pivotal trial satisfied the specifications of the Protocol Agreement with the FDA under which it was conducted," said Joseph V. Gulfo, MD, President & CEO. "We look forward to working with the FDA in the review of the MelaFind application."

44. The statements made by Defendants and contained in the Company's June 4, 2009 release and those statements contained in the Company's Form 10-Q were each materially false and misleading when made, and were known by defendants to be false at that time or were recklessly disregarded as such thereby for the reasons stated herein in ¶39, *supra*.

45. Taking further advantage of the artificial inflation in the price of Company shares caused as a result of Defendants' publication of materially false and misleading information, on or about July 17, 2009, Defendants announced that MELA had registered for sale and sold an additional \$15 million of Company stock. That day, Defendants published a release that stated, in part, the following:

Electro-Optical Sciences Announces \$15 Million Registered Direct Offering IRVINGTON, NY, July 17, 2009 (MARKETWIRE via COMTEX) – ElectroOptical Sciences, Inc. ("EOS") (NASDAQ: MELA), today announced that it has entered into definitive agreements with a select group of institutional investors to sell 2,400,000 shares of common stock at a negotiated purchase price of \$6.25 per share in a registered direct offering. The transaction is expected to close on or about July 22, 2009, subject to the satisfaction of customary closing conditions.

The offering will result in gross proceeds of \$15 million to EOS before deducting placement agents' fees and estimated offering expenses. EOS intends to use the net proceeds from the sale of the shares to fund pursuit

of its pre-market approval application (PMA) for MelaFind®, the continued development and, if and when approved by the U.S. Food and Drug Administration (FDA), the commercialization of MelaFind®, and for general corporate purposes, including working capital.

All of the shares of common stock are being offered pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission (the “SEC”) which was declared effective on July 7, 2008.

46. On July 24, 2009, the Company filed its Form 10-Q, for the second quarter ended June 30, 2009, signed by Defendant Steinhart, and certified by Defendants Gulfo and Steinhart. Again, the Company’s report conditioned investors to believe that MelaFind received “positive top line results from the MelaFind pivotal clinical trial,” and reminded investors that, “[o]n June 3, 2009, the Company submitted the MelaFind Pre-Market Approval Application to the FDA.”

47. In addition to the foregoing, the Form 10-Q again conditioned investors to believe that the Company maintained an adequate system of internal controls, as follows:

#### **ITEM 4. Controls and Procedures**

##### **Evaluation of disclosure controls and procedures**

Based on their evaluation as of June 30, 2009, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

48. The Form 10-Q again contained Certifications by Defendants Gulfo and Steinhart that continued to certify that the information contained in the Form 10-Q “fairly presents, in all material respects, the financial condition and results of operations of the Company,” as follows:



**ELECTRO-OPTICAL SCIENCES INC.  
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of Electro-Optical Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's quarterly report on Form 10-Q for the period ended June 30, 2009 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo  
Joseph V. Gulfo  
President and Chief Executive Officer  
(Principal Executive Officer)

July 24, 2009

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)

July 24, 2009

49. Following the filing of the Form 10-Q, however, the SEC contacted the Company and complained that defendants had not properly documented their disclosure controls and procedures. In this regard, the SEC informed the Company, in part, as follows:

We note your statement that your chief executive officer and chief financial officer have concluded that your disclosure controls and procedures were "sufficiently effective." It does not appear that your certifying officers have reached a conclusion that your disclosure controls and procedures are *effective*. Please confirm to us that disclosure controls were effective at June 30, 2009 and revise future filings to clearly address your officers' conclusions regarding the effectiveness of your disclosure controls and procedures.



50. To further condition investors - - and the SEC - - to believe that the Company had maintained the proper system of internal controls and procedures, on October 7, 2009, Defendants responded to the SEC, in part, as follows:

The Company confirms that its disclosure controls and procedures were effective at June 30, 2009. We will revise future filings to clearly address our officers' conclusions regarding the effectiveness of our disclosure controls and procedures.

The Company acknowledges that: (i) the Company is responsible for the adequacy and accuracy of the disclosure in the filing, (ii) Staff comments or changes to disclosure in response to Staff Comments do not foreclose the Commission from taking any action with respect to the filing; and (iii) the Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

51. The statements made by Defendants and contained in the Company's October 7, 2009 response to the SEC and those statements contained in the Company's Form 10-Q were each materially false and misleading when made, and were known by Defendants to be false at that time or were recklessly disregarded as such thereby for the reasons stated herein in ¶39, *supra*.

52. On November 9, 2009, the Company filed its Form 10-Q, for the third quarter ended September 30, 2009, signed by defendant Steinhart, and certified by Defendants Gulfo and Steinhart. Again, the Company's report conditioned investors to believe that MelaFind received "positive top line results from the MelaFind pivotal clinical trial," and reminded investors that, "[o]n June 3, 2009, the Company submitted the MelaFind Pre-Market Approval Application to the FDA."

53. In addition to the foregoing, the Form 10-Q again conditioned investors to believe that the Company maintained an adequate system of internal controls, as follows:

#### **ITEM 4. Controls and Procedures**

##### **Evaluation of disclosure controls and procedures**

Based on their evaluation as of September 30, 2009, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

54. The Form 10-Q again contained Certifications by Defendants Gulfo and Steinhart that continued to certify that the information contained in the Form 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company," as follows:

**ELECTRO-OPTICAL SCIENCES, INC.  
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of Electro-Optical Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's quarterly report on Form 10-Q for the period ended September 30, 2009 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo  
Joseph V. Gulfo  
President and Chief Executive Officer  
(Principal Executive Officer)

November 9, 2009

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)

November 9, 2009

55. The statements made by Defendants and contained in the Company's Form 10-Q were each materially false and misleading when made, and were known by defendants to be false at that time or were recklessly disregarded as such thereby for the reasons stated herein in ¶39, *supra*.

56. On March 4, 2010, the Company filed its Form 10-K for the fiscal year ending December 31, 2009, signed by Defendants Gulfo, Steinhart and Castleman and certified by Defendants Gulfo and Steinhart. Again, the Company's report conditioned investors to believe that MelaFind received "positive top line results from the MelaFind pivotal clinical trial," and reminded investors that, "[o]n June 3, 2009, the Company submitted the MelaFind Pre-Market Approval Application to the FDA."

57. In addition to the foregoing, the 2009 Form 10-K again conditioned investors to believe that the Company maintained an adequate system of internal controls, as follows:

**Item 9A. Controls and Procedures**

***Evaluation of disclosure controls and procedures***

Our company's management, with the participation of our chief executive officer and our chief financial officer, has evaluated the effectiveness of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities and Exchange Act of 1934) as of December 31, 2009.

Based on such evaluation, our chief executive officer and our chief financial officer have concluded that, as of December 31, 2009, our disclosure controls and procedures were effective to ensure that the information we are required to disclose in reports that we file or submit to the SEC is (1) recorded, processed, summarized and reported within the time periods specified under the rules and forms of the SEC and (2) accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

58. The 2009 Form 10-K again contained Certifications by Defendants Gulfo and Steinhart that continued to certify that the information contained in the 2009 Form 10-K "fairly

presents, in all material respects, the financial condition and results of operations of the Company," as follows:

**ELECTRO-OPTICAL SCIENCES, INC.  
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANE8-OXLEY ACT OF 2002**

Each of the undersigned officers of Electro-Optical Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's quarterly report on Form 10-Q for the period ended December 31, 2009 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo  
Joseph V. Gulfo  
President and Chief Executive Officer  
(Principal Executive Officer)

March 3, 2010

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)

March 3, 2010

59. On March 24, 2010, the Company issued a press release designed to again reassure investors concerning the safety and efficacy of MelaFind. This release was especially important given that it purported to respond to specific issues noted by the FDA. Accordingly, this release stated, in part, the following:

IRVINGTON, NY, (March 24, 2010) - MELA Sciences (NASDAQ: MELA) today announced that it has received additional questions from U.S. Food and Drug Administration (FDA) regarding the review status of the Pre-Market Approval (PMA) application of its MelaFind device for early melanoma detection. The company is actively working to respond to

the agency's questions in the immediate term. The FDA indicated that the MelaFind PMA review has been extended 180 days.

\* \* \*

The PMA application is based on the positive results of the company's landmark pivotal study, which included 1,831 pigmented skin lesions from 1,383 patients, making this the largest prospective study ever conducted in melanoma detection. Prior to the start of the study, the company and the FDA entered into a binding protocol agreement to stipulate the study design, including the sensitivity and specificity endpoints that should be used to determine the safety and effectiveness of MelaFind.

*"We believe our data satisfy the study's agreed-upon endpoints and we will continue to work with the agency to move the approval process forward," Dr. Gulfo said.*

"MelaFind is a breakthrough product with the potential to save lives," Dr. Gulfo said. "Dermatologists in market research exercises, as well as our expert dermatology consultants, tell us that MelaFind can provide great help in their effort to detect melanoma, which kills one American per hour, at the earliest most curable stages. We believe an FDA Panel meeting is important to our review, and are confident that it would greatly expedite the PMA review process, and so, we will continue to focus on obtaining a Panel meeting for MelaFind as soon as possible." [Emphasis added].

60. The statements made by Defendants and contained in the Company's March 24, 2010 release and those statements contained in the Company's 2009 Form 10-K were each materially false and misleading when made, and were known by defendants to be false at that time or were recklessly disregarded as such thereby for the reasons stated herein in ¶39, *supra*.

61. On May 10, 2010, the Company filed its Form 10-Q, the period ended March 31, 2010, signed by Defendant Steinhart and certified by Defendants Gulfo and Steinhart. Again, the Company's report conditioned investors to believe that the Company maintained an adequate system of internal controls, as follows:



**ITEM 4.**

**Controls and Procedures**

**Evaluation of disclosure controls and procedures**

Based on their evaluation as of March 31, 2010, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

62. The Form 10-Q again contained Certifications by Defendants Gulfo and Steinhart that continued to certify that the information contained in the Form 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company," as follows:

**ELECTRO-OPTICAL SCIENCES, INC.  
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of Electro-Optical Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's quarterly report on Form 10-Q for the period ended March 31, 2010 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo  
Joseph V. Gulfo  
President and Chief Executive Officer  
(Principal Executive Officer)

May 10, 2010

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)

May 10, 2010

63. On May 26, 2010, the Company, in an apparent attempt to further prime the market about MelaFind and its progress, issued a press release that not only emphasized once again the February 2009 positive results, but also stated, in part, the following:

IRVINGTON, NY (May 26, 2010) - MELA Sciences, Inc. (Nasdaq: MELA) announced today that the company's pre-market approval (PMA) application for MelaFind® will be reviewed by the General and Plastic Surgery Devices Panel appointed by the U.S. Food and Drug Administration (FDA) on August 26, 2010.

*"We are so pleased to see the MelaFind review process move forward," said Joseph V. Gulfo, M.D., President & CEO. "We and our advisors look forward to the Panel meeting with great anticipation. We have had positive and constructive interactions with the agency culminating in the submission of our formal response to the FDA's questions regarding the PMA application earlier this month. We are now fully focused on preparing for the August 26th panel meeting and firmly believe that MelaFind will be found to be a valuable tool to help dermatologists detect melanoma at the earliest, most curable stage."*

The company also reported the results of its internet-based US reader study performed by 155 physicians, including 110 dermatologists, on images and clinical information derived from 130 lesions (melanomas and non-melanomas) enrolled in the MelaFind pivotal trial. The average sensitivity of dermatologists was 72%. *The sensitivity of MelaFind was 96.9%, which was statistically significantly superior to dermatologists at value of less than 0.0001. The Company plans to submit the results of the reader study to a peer review journal for publication.*

The panel will review the MelaFind PMA application, which the company submitted to the agency in June 2009. It is based on the positive results of the company's landmark pivotal study, which included 1,831 pigmented skin lesions from 1,383 patients, making this the largest prospective study ever conducted in melanoma detection. Prior to the start of the study, the company and the FDA entered into a binding protocol agreement to stipulate the study design, including the sensitivity and specificity endpoints that should be used to determine the safety and effectiveness of

MelaFind. *The company believes that the results of the pivotal study met and exceeded the pre-defined endpoints.* [Emphases added].

64. Taking further advantage of the artificial inflation in the price of Company shares caused as a result of defendants' publication of materially false and misleading information, on or about June 30, 2010, defendants filed a Form 424B5 with the SEC to offer for sale 2.53 million shares of its common stock priced at \$7.50 per share, including 330,000 shares to cover over allotments, to raise gross proceeds of \$18.975 million. According to Defendants, the offering was expected to close on July 6, 2010 subject to the satisfaction of customary closing conditions.

65. The day before this offering, however, on June 29, 2010, in a conference call for investors and analysts, an investor asked Defendant Gulfo specifically if FDA reviewers agreed with the Company's statistical analysis of the MelaFind phase III study results. The investor on the call wanted to know why, if the study's endpoints were met, did FDA deem MelaFind "not approvable last March. *In response, Gulfo said not to assume that FDA's non-approvable letter last March was related to problems the agency had with MELAFind's accuracy.* At that time, Defendant Gulfo described many of the FDA's questions about MelaFind as "typical," adding the company was happy that FDA scheduled an advisory panel meeting for August. [Emphases added].

66. The statements made by Defendants and contained in the Company's May 26, 2010 release, those statements made in during the Company's June 28, 2010 conference call and those statements contained in the Company's Form 10-Q were each materially false and misleading when made, and were known by Defendants to be false at that time or were recklessly disregarded as such thereby for the reasons stated herein in ¶39, *supra*.

67. On August 6, 2010, the Company filed its Form 10-Q, the period ended June 30, 2010, signed by Defendant Steinhart and certified by Defendants Gulfo and Steinhart. Again, the Company's report conditioned investors to believe that the Company maintained an adequate system of internal controls, as follows:

**ITEM 4.**

**Controls and Procedures**

**Evaluation of disclosure controls and procedures**

Based on their evaluation as of June 30, 2010, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

68. The Form 10-Q again contained Certifications by Defendants Gulfo and Steinhart that continued to certify that the information contained in the Form 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company," as follows:

**MELA SCIENCES, INC. CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of MELA Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's quarterly report on Form 10-Q for the period ended June 30, 2010 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.



/s/ Joseph V. Gulfo  
Joseph V. Gulfo  
President and Chief Executive Officer  
(Principal Executive Officer)

August 6, 2010

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)

August 6, 2010

69. The statements made by defendants and contained in the Company's Form 10-Q were each materially false and misleading when made, and were known by Defendants to be false at that time or were recklessly disregarded as such thereby for the reasons stated herein in ¶39, *supra*.

70. On November 5, 2010, the Company filed its Form 10-Q, the period ended September 30, 2010, signed by Defendant Steinhart and certified by Defendants Gulfo and Steinhart. Again, the Company's report conditioned investors to believe that the Company maintained an adequate system of internal controls, as follows:

**ITEM 4.**

**Controls and Procedures**

**Evaluation of disclosure controls and procedures**

Based on their evaluation as of September 30, 2010, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.



71. The Form 10-Q again contained Certifications by Defendants Gulfo and Steinhart that continued to certify that the information contained in the Form 10-Q “fairly presents, in all material respects, the financial condition and results of operations of the Company,” as follows:

**MELA SCIENCES, INC. CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of MELA Sciences, Inc. (the “Company”) hereby certifies to his knowledge that the Company’s quarterly report on Form 10-Q for the period ended September 30, 2010 (the “Report”), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo  
Joseph V. Gulfo  
President and Chief Executive Officer  
(Principal Executive Officer)

November 5, 2010

/s/ Richard I. Steinhart  
Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)

November 5, 2010

72. The statements made by Defendants and contained in the Company’s Form 10-Q were each materially false and misleading when made, and were known by Defendants to be false at that time or were recklessly disregarded as such thereby for the reasons stated herein in ¶39, *supra*.

**THE TRUTH IS REVEALED**

73. On November 16, 2010, before the market opened, the FDA released documents stating that “[t]he FDA review team has significant concerns this device has not been studied

adequately for its current indication for use and therefore puts the health of the public at risk.” In particular, FDA reviewers were concerned about the device’s accuracy rate and have recommended that an additional study be conducted. That day, Reuters reported - in an article entitled, “UPDATE 3-FDA reviewers criticize Mela skin cancer device” - that the FDA had indicated that MelaFind was unproven and could cause harm; that MELA needed a new clinical trial for the device; and that MELA would need to raise new capital. The article further stated, in part:

WASHINGTON, Nov 16 (Reuters) - U.S. health regulators said Mela Sciences Inc.’s (MELA) experimental device to help diagnose deadly skin cancer *could cause harm because of the potential for misdiagnosis*, wiping out more than half of the company’s market value.

*FDA staff pointed to numerous problems with Mela’s study of the device, caused MelaFind, including a significant lack of data, and urged a new clinical trial. But analysts saw major stumbling blocks ahead and were doubtful the company had enough resources to conduct another study.*

“The FDA review team has significant *concerns this device has not been studied adequately for its current indications for use and there/ore puts the health of the public at risk*,” the U.S. Food and Drug Administration said in documents released on Tuesday.

\* \* \*

The documents were released ahead of an FDA advisory panel meeting Thursday to weigh whether to approve the device for use in detecting melanoma....

The concerns raised by the FDA staff are “problematic at its best” and investors should be warned, WBB Securities analyst Steve Brozak said.

“This now comes down to two main questions -- does Mela have enough resources to address the issues and, if not, what is the salvage value of the technology,” Brozak added.

\* \* \*

Boerming & Scattergood analyst Greg Chodaczek said the company would need to raise money to do a new trial.

74. On this news, MELA's stock price fell on November 16, 2010 to close at \$2.92 from the previous day's closing price of \$6.37, a drop of approximately 54% on heavy trading volume, as investors began to learn the truth concealed by defendants during the Class Period. This decline resulted directly from the removal of some of the artificial inflation in the price of MELA stock caused by Defendants' misstatements and omissions.

75. The following day, November 17, 2010, *TheStreet.com* also published an article entitled, "MELA Sciences is Doomed," which stated, in part, the following:

The FDA panel's experts will vote against MELAFind because the FDA has already made it very clear that *the noninvasive computerized imaging device, as studied, doesn't work and may actually harm patients.*

I don't feel the need to hedge my prediction of a MELAFind rout tomorrow. I've read a lot of damning reviews of experimental drugs and medical devices conducted by FDA in my ten years covering the biotech beat, but *I cannot remember any FDA review until MELAFind in which the agency states flatly that approval could hurt patients.*

Yet that's what FDA concluded about MELAFind in a review of the device released Tuesday. *The FDA's warning is alarming:*

"FDA's Mission is to Protect and Promote the Public Health and the FDA review team has significant concerns *this device has not been studied adequately for its current indications for use and therefore puts the health of the public at risk,*" FDA concluded.

\* \* \*

I've been questioning MELAFind's accuracy for months but even *I was surprised at the ferociousness by which FDA attacked MELA Science and the device.*

*The FDA, in its review; accuses the company of reneging on an agreement to study the device in certain patients at risk for melanoma. The FDA concluded that data from a pivotal study showed MELAFind to be less accurate than trained dermatologists in detecting potentially deadly melanoma raising the risk of misdiagnosis. And MELAFind's benefit was "clinically meaningless" because the device does not reduce the number of biopsies and in fact. May actually force doctors to perform more biopsies. FDA found.*

76. On November 17, 2010, MELA's stock price fell an additional 13% to close that day at \$2.53.

### **CAUSATION AND ECONOMIC LOSS**

77. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market, and a course of conduct that artificially inflated MELA's stock price and operated as a fraud or deceit on Class Period purchasers of MELA's stock by misrepresenting the status of MelaFind's ongoing clinical studies, its efficacy, and prospects for FDA approval. Ultimately, however, when Defendants' prior misrepresentations and fraudulent conduct came to be revealed to investors, shares of MELA declined precipitously -- evidence that the prior artificial inflation in the price of MELA's shares was eradicated. As a result of their purchases of MELA stock during the Class Period at artificially inflated prices, plaintiffs and other members of the Class suffered economic losses when the Company's true condition and the truth about MelaFind was finally and fully revealed and the artificial inflation was removed from price of the Company's stock, *i.e.*, damages under the federal securities laws.

78. By improperly characterizing MelaFind's efficacy and prospects for FDA approval, the Defendants presented a misleading image of MELA and its future business prospects. During the Class Period, Defendants repeatedly emphasized the purported accuracy and completeness of the Company's representations, as well as the purported effectiveness of the Company's disclosure controls and procedures. These claims caused and maintained the artificial inflation in MELA's stock price throughout the Class Period, until the truth about the Company and MelaFind were ultimately revealed to investors. As the truth became known to investors, these disclosures had an immediate, adverse impact on the price of MELA shares.

79. These belated revelations also evidenced Defendants' prior falsification of MELA's business prospects due to Defendants' false statements. As investors and the market ultimately learned, MelaFind's efficacy and prospects for FDA approval and, thus, the Company's business prospects had vastly been overstated or falsely stated. As this adverse information became known to investors, the prior artificial inflation began to be eliminated from MELA's share price and the members of the Class were damaged as a result of the related share price decline.

80. The decline in MELA's stock price at the end of the Class Period was a direct result of the nature and extent of Defendants' fraud being revealed to investors and to the market. The timing and magnitude of MELA's stock price decline negates any inference that the losses suffered by plaintiffs and the other members of the Class were caused by changed market conditions, macroeconomic or industry factors, or even Company-specific facts unrelated to Defendants' fraud.

**Applicability Of Presumption Of Reliance:  
Fraud-On-The-Market Doctrine**

81. At all relevant times, the market for MELA securities was an efficient market for the following reasons, among others:

(a) MELA's stock met the requirements for listing, and was listed and actively traded on the Nasdaq national market exchange, a highly efficient and automated market;

(b) As a regulated issuer, MELA filed periodic public reports with the SEC and the Nasdaq;

(c) MELA regularly communicated with public investors *via* established market communication mechanisms, including through regular disseminations of press releases



on the national circuits of major newswire services and through other wide-ranging public disclosures; and

(d) MELA was followed by securities analysts employed by major brokerage firm(s) who wrote research reports, which were publicly available and entered the public marketplace.

82. As a result of the foregoing, the market for MELA securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in MELA's stock price. Under these circumstances, all purchasers of MELA securities during the Class Period suffered similar injury through their purchases of MELA securities at artificially inflated prices and a presumption of reliance applies.

#### **NO SAFE HARBOR**

83. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded herein. Many of the specific statements pleaded were not identified as "forward-looking statements" when made. To the extent that any alleged misstatements are forward-looking, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of MELA who knew that those statements were false or lacked any reasonable basis when made.

**BASIS OF ALLEGATIONS**

84. Plaintiffs have alleged the following based upon the investigation of plaintiffs counsel, which included a review of SEC filings by MELA, as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

**FIRST CLAIM**

**Violation Of Section 10(b) Of  
The Exchange Act And Rule 10b-5  
Promulgated Thereunder Against All Defendants**

85. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

86. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and throughout the Class Period, did: (a) deceive the investing public regarding the Company's business operations, management, future business prospects and the intrinsic value of MELA's common stock; (b) deceive the investing public regarding MELA's business and management; (c) deceive the investing public regarding the efficacy of MelaFind and its prospects for FDA approval; (d) enable Defendants to sell almost \$79 million of MELA's common stock to the public while in possession of material adverse non-public information about the Company; and (e) cause plaintiffs and other members of the Class to purchase MELA securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, jointly and individually took the actions set forth herein.

87. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and, (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein and/or as controlling persons as alleged below.

88. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations, and future prospects of MELA as specified herein.

89. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (a) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (b) each of these Defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections, and/or reports; (c) each of these Defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports, and other data and information about the status of MelaFind's ongoing clinical studies and prospects for FDA approval; and, (d) each of these Defendants was aware of the Company's dissemination of information to the investing public, which they knew or recklessly disregarded was materially false and misleading

when made.

90. The Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly for the purpose and effect of concealing MELA's true condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements regarding the status of MelaFind's ongoing clinical studies, efficacy, and prospects for FDA approval throughout the Class Period, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were severely reckless in failing to obtain such knowledge by refraining from taking those steps necessary to discover whether those statements were false or misleading.

91. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of MELA securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of MELA's publicly-traded common stock were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public, plaintiffs and the other members of the Class acquired MELA securities during the Class Period at artificially high prices and were damaged thereby.

92. At the time of said misrepresentations and omissions, plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had plaintiffs

and the other members of the Class known the truth regarding MELA and MelaFind, which were not disclosed by Defendants, plaintiffs and other members of the Class would not have purchased their MELA securities, or if they had, they would not have done so at the artificially inflated prices paid.

93. As a direct and proximate result of Defendants' wrongful conduct, plaintiffs and the other members of the Class suffered damages in connection with their respective purchases of the Company's securities during the Class Period.

94. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

## **SECOND CLAIM**

### **Violation of Section 20(a) of The Exchange Act Against Individual Defendants**

95. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

96. The Individual Defendants acted as controlling persons of MELA within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false statements regarding MelaFind filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements, which plaintiffs contends are materially false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by plaintiffs to be materially



misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

97. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and to have exercised the same.

98. As set forth above, MELA and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this complaint. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities at artificially inflated prices during the Class Period. As such, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

**WHEREFORE**, plaintiffs pray for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure, designating plaintiffs as Lead Plaintiff, and approving plaintiffs' counsel as Lead Counsel;

B. Awarding compensatory damages in favor of plaintiffs and the other Class Members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding extraordinary, equitable and/or injunctive relief as permitted by law, equity and the federal statutory provisions sued hereunder, pursuant to Rules 64 and 65, and any appropriate state law remedies to assure that the Class has an effective remedy; and

E. Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiffs hereby demand a trial by jury.

Dated: January 20, 2011

**POMERANTZ HAUDEK  
GROSSMAN & GROSS LLP**

By: 

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*Counsel for Plaintiffs*

**Certification of Plaintiff**  
**Pursuant to Federal Securities Laws**

1. We, Martin Slove and Linda Slove, make this declaration pursuant to Section 101 of the Private Securities Litigation Reform Act of 1995 as required by Section 21D (a) (2) of Title I of the Securities Exchange Act of 1934.

2. We have reviewed a Complaint against MELA Sciences, Inc.. ("MELA"), and authorize a filing of a comparable complaint on our behalf.

3. We did not purchase our MELA securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under Title I of the Securities Exchange Act of 1934.

4. We are willing to serve as a representative party on behalf of a class as set forth in the Complaint, including providing testimony at deposition and trial, if necessary. We understand that the Court has the authority to select the most adequate lead plaintiff in this action and that the Counsel will exercise its discretion in determining whether to move on our behalf for appointment as lead plaintiff.

5. To the best of our current knowledge, the attached sheet lists all of my purchases and sales in MELA securities during the Class Period as specified in the Complaint.

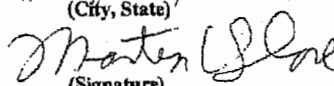
6. During the three-year period preceding the date on which this certification is signed, we have not sought to serve as a representative party on behalf of a class under the federal securities laws, except as follows:

7. We agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

8. The matters stated in this declaration are true to the best of my current knowledge, information and belief.

We declare under penalty of perjury that the foregoing is true and correct.

Executed 12/3/10, at \_\_\_\_\_,  
(Date) (City, State)

Westfield, NJ  
(City, State)  
  
(Signature)  
MARTIN L. SLOVE  
(Type or Print Name)

Executed \_\_\_\_\_, at \_\_\_\_\_,  
(Date) (City, State)

(City, State)

(Signature)

(Type or Print Name)

MELA SCIENCES INC

SLOVE, MARTIN  
and LINDA

## LIST OF PURCHASES AND SALES

DATE	PURCHASE OR SALE	NUMBER OF SHS/UTS	PRICE PER SH/UT
2/26/2009	PUR Com Stk	1,000	\$4.0400
3/25/2009	PUR Com Stk	4,000	\$3.6900
11/19/2009	SLD Com Stk	27,000	\$5.0000
8/23/2010	SLD Put 7.50 01/11	401	\$2.8100
8/26/2010	PUR Put 10.00 01/11	750	\$5.5800
8/26/2010	SLD Put 10.00 01/11	750	\$4.6000
9/2/2010	PUR Put 12.50 04/11	100	\$9.6000
9/2/2010	SLD Put 12.50 04/11	100	\$7.3000
11/15/2010	PUR Put 7.50 01/11	401	\$5.3000